

Equipment Specification Data Sheet

Equipment Name: Online Particle Counter
(non-viable)

Document No.: DS-OPC 01

Revision: 02

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F1	Viral Vaccine Formulation - Rabies	F1-OPC 01	-	1
F1	Viral Vaccine Formulation - Measles	F1-OPC 02	-	1
F2	Bacterial Vaccine Formulation	F2-OPC 01	-	1
F4	BCG Bulk and Formulation Block	F4-OPC 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Ms. Shashikala	Sr. Engineer - Process	<i>Shashikala</i>	7/03/2016
Checked by			
Mr. Yogesha M J	Process Engineer	<i>Yogesha-MJ</i>	7/03/2016
Approved by			
Mr. Krishna Amrutham	Lead Engineer - Fill Finish	<i>Krishna Amrutham</i>	7/03/2016

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HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
NAVIA KUMAR. P (VVF - Rabies)	DY. MANAGER (VVF)		08/03/16
User department: K. RAJAKRISHNAN (VVF - Rabies)	DY. MANAGER (PRODUCTION)		08/03/16
for User department: C. RAJESH (BVF)	Assistant manager		08-03-2016
User department: Elayavani. K (Formulation)	Proj Asst		8.03.2016
HARSHAD DABHI Engineering department	DY. MANAGER	H.B. Dabhi	08/03/16
QA Jayakandan	Sr. Manager, QA		08-03-16
Approved by			
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Dr. R. Lakshmi (VVF - Measles)	DVP		
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Head of the department Ranjith. M. C (Formulation)	Manager		
Head of the department A. Suresh Babu	Asst		08.03.16
Authorized by			
Raman K Ramachan -dhan	CEO		08/03

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HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Online Particle Counter (non-viable)
	Document No.	DS-OPC 01
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1	Process requirements	
1.1	The Online Particle Counters shall be used for continuous monitoring of the Non Viable Particles in the critical areas of filling line. Particle counter system shall be installed for four different vial filling lines. The number of sensors required at different locations of the each filling line are described in the annexure of this document.	
2	Equipment ID	
2.1	F1-OPC 01	
2.2	F1-OPC 02	
2.3	F2-OPC 01	
2.4	F4-OPC 01	
3	Technical Specification	
3.1	Channels	Two channel mode: 0.5µm and 5.0µm,
3.2	Standard Flow rate	1.0 ft ³ / min
3.3	Zero Count filter	0.2 micron absolute with tubing on all sensors
3.4	Maximum particle concentration	<i>Vendor shall specify</i>
3.5	Vacuum Source	Internal dry vacuum pump with suitable motor (dedicated for each sensor)
3.6	Sampling Probe (Isokinetic)	<i>Vendor shall specify the size</i>
3.7	Laser Diode	Class 1 Laser Devices
3.8	Sensor optics	Shall be VHP Resistant type
3.9	Calibration	ISO 21501-4 required
3.10	Software	<i>Vendor shall consider and specify the suitable software (cost of software shall be included in the quote)</i>
3.11	PC for software	<i>Software control with SCADA base for remote monitoring.</i>
3.12	Dimensions of sensor cabinet (W x H x D)	<i>Vendor to specify</i>
3.13	Electrical Requirement	<i>Vendor to specify</i>
3.14	Output	<i>RS-232 / ethernet with SCADA facility for monitoring and controlling.</i>
3.15	Weight	<i>Vendor to specify</i>
4	Material of Construction	
4.1	Enclosure Box	SS 304
4.2	Isokinetic Probe	SS 316L
4.3	Probe holder	SS 304
4.4	Tube	GMP Compliant
5	Specific Equipment Requirements	
5.1	Probable locations: sensors should be fixed in the following areas of vial filling line area <ul style="list-style-type: none"> • Infeeder/ Infeed conveyor • Filling Station • Stoppering station • Lyophiliser Loading/ unloading LAF (Ceiling suspended LAF) • Background (for Grade B) Refer Annexure-1 for the locations of the sensors in the filling line	

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5.2	Redundant Server is required. Automatic Buffer Data recovery during switching over shall be considered.	
5.3	Turbulence shall be avoided in the in the sampling flow.	
5.4	Suitable trend analysis and graph shall be provided.	
5.5	Each particle counter system (for each filling line) shall be provided with suitable software for data processing and SCADA system (Refer Online Particle Counter Architecture provided as annexure-2)	
5.6	SCADA system shall have provision of integrating the online temperature and relative humidity sensors in future.	
5.7	Vacuum pump shall have HEPA filter at exhaust	
5.8	Alarms shall be provided at following situations - System detects sample probe capped while pump is ON - Flow Failure (vacuum pump) - Communication Failure - Count Alarm /Alert - Sensor Contamination	
5.9	The system shall include all associated hardware, cabinet and required license	
5.10	Flow rate indicator: Differential Pressure transducer with LED indicator shall be provided	
5.11	Four Visual indicators on the front of the unit: LED power, count, laser status and flow status	
5.12	The system shall be capable to generate a variety of standard reports defined by industry standards, such as EU GMP Annex 1 (2008) / FS 209E / ISO 14644	
5.13	Supports for probe mounting for the filling line shall be provided by filling line supplier however probe Holding arrangement for Background (grade B) & Lyo area to be provided by particle counter supplier.	
5.14	Vendor to consider and quote for the following: Data acquisition / logging cable (in Rmt) and tubing laying/ termination. Computer, computer hardware and printer (inkjet, color). (The particle counter system cables should run through separate duct-Cable tray to be considered (if required)as part of scope of supply)	
5.15	The cable shall be insulated to prevent the loss of data.	
5.16	Vendor to provide the computer with following minimum specification Monitor - 14 inch RAM - 4 GB Hard drive - 200 GB Processor- intel i3-3220 Processor (3.30 GHz) It shall be compatible with windows xp, Windows 7 and Windows 8 or latest operating system. (Refer annexure:2 for details on the no. of PC and printers)	
6	Other requirement	
6.1	System shall have communication cable - RS 232 / RJ45 / ethernet cable for connecting to the additional printer	
6.2	Tricolor alarm tower shall be integrated to all the system and the required hardware shall be provided. (Audio and Visual type)	
6.3	Vendor shall provide the option to monitor the flow rate continuously both in cubic foot and cubic meter	
6.4	Isokinetic sampling probes shall be installed at a maximum distance of 1 feet away from the point of risk to product.	
7	Regulatory aspects	
7.1	21 CFR part 11 compliance	
7.2	The system shall be compliance with ISO standards and CE standards	
7.3	Factory Prime calibration with NIST traceable standards in accordance with ASTM F-328 and JIS B9921 Exceeds ISO21501	
8	Safety requirements	

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8.1	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.	
8.2	Proper earthing of the equipment.	
9	Documents	
Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy		
9.1	DQ Document	
9.2	IQ / OQ Protocol	
9.3	Operational Manual	
9.4	MOC certificates	
9.5	List of MAKE with certificate (to be used during fabrication of this unit)	
9.6	Cable line diagram to be provided by vendor.	
9.7	Warranty certificate for minimum of 1 year from the date of completion	
10	Timelines	
	Not Applicable	
11	Preferred List of Makes	
11.1	PMS, Met-One, TSI	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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Table-1: Equipment location

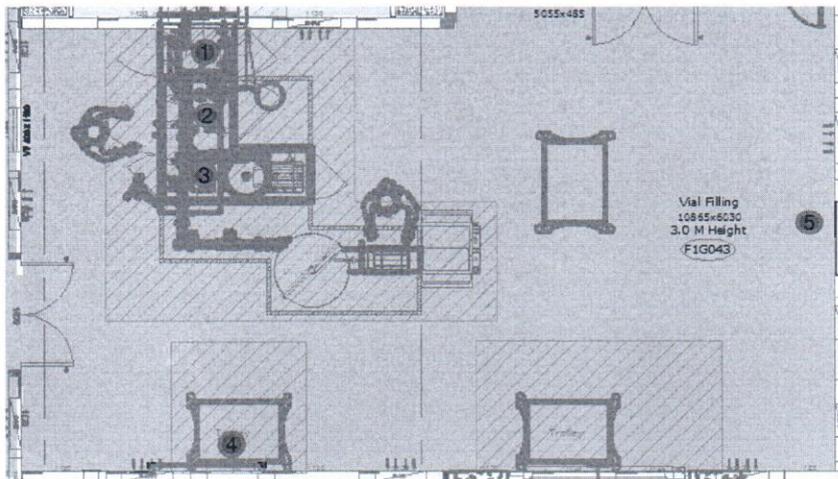
Equipment ID	Block Name	Room Name	Room No	Room dimension (L x W) in mm	False ceiling height in mm
F1-OPC 01	VVF - Rabies	Vial Filling	F1G043	1086 X 6030	3000
F1-OPC 02	VVF - Measles	Vial Filling	F1G086	10865 X 6030	3000
F2-OPC 01	BVF	Filling Room	F2G044	7350 X 12800	3000
F4-OPC 01	BCG	Vial Filling & Lyo loading and unloading And Crimping Area	F4G040	7700 X 6700 & 5150 X 10350	3000

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
25-01-2016	Shashikala	00	-	New document
10-02-2016	Yogesha M J	01	All	Updated as per comments given by HBL dated 09-02-2016 by mail
02-03-2016	Yogesha M J	02	-	Updated as per comments given by HBL dated 01-03-2016 by mail

Table-3: Annexure: 1

F1-OPC 01: Viral Vaccine Formulation - Rabies	
Particle counter No.	Location
1	In-Feed to filling and stoppering machine
2	Vial Filling station near filling needles
3	Vial Stoppering Station
4	Lyophiliser Loading/ unloading LAF
5	Background Area (for Grade B)



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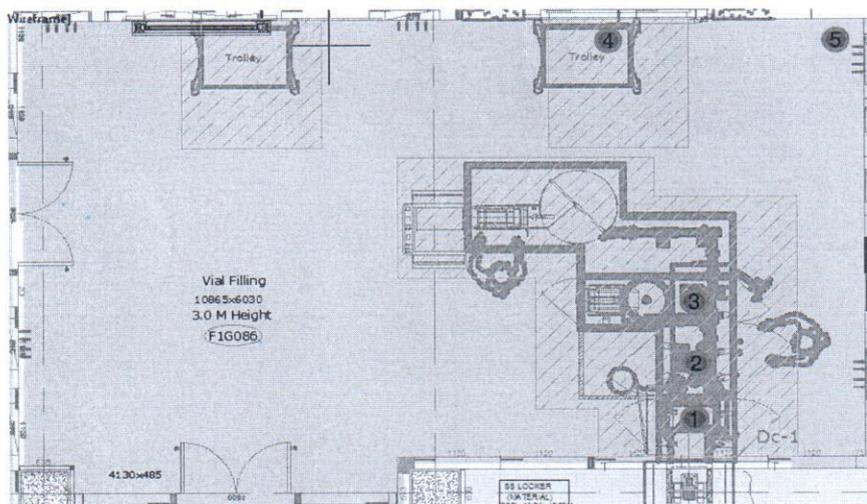
Document No. DS-OPC 01

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F1-OPC 02: Viral Vaccine Formulation - Measles

Particle counter No.	Location
1	In-Feed to filling and stoppering machine
2	Vial Filling station near filling needles
3	Vial Stoppering Station
4	Lyophiliser Loading/ unloading LAF
5	Background Area (for Grade B)



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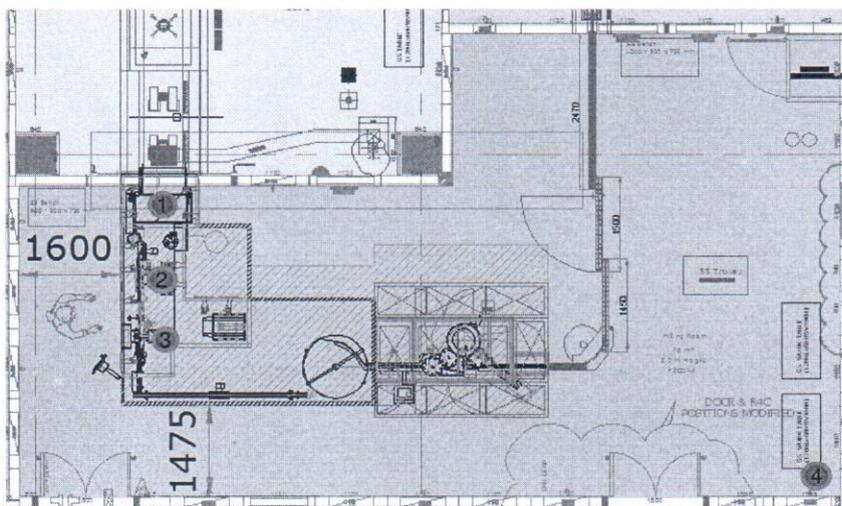
Document No. DS-OPC 01

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F2-OPC 01: Bacterial Vaccine Formulation

Particle counter No.	Location
1	In-Feed to filling and stoppering machine
2	Vial Filling station near filling needles
3	Vial Stoppering Station
4	Background Area (for Grade B)



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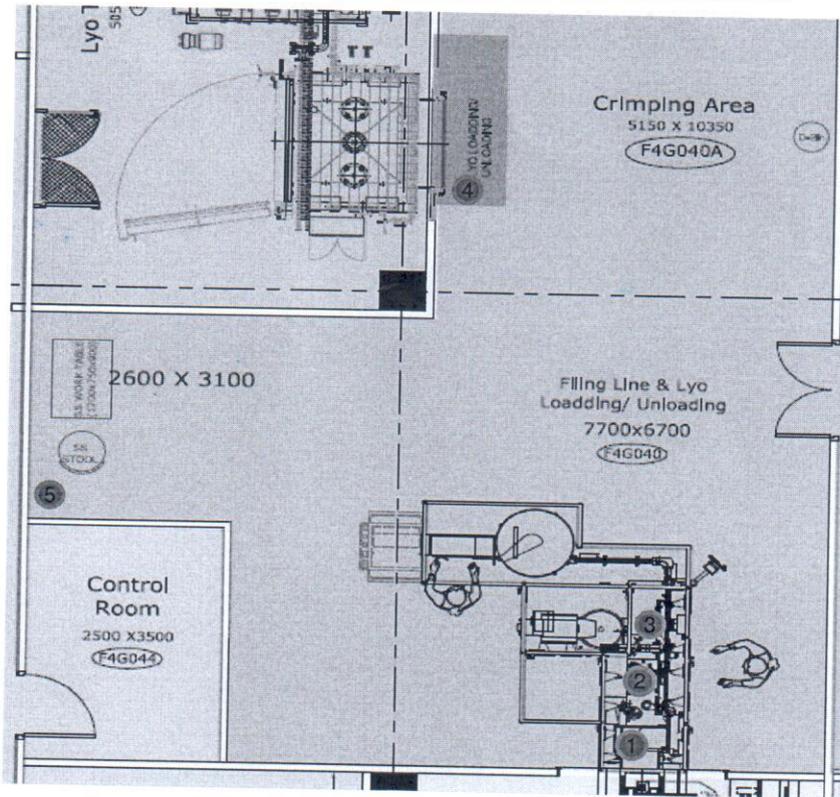
Document No. DS-OPC 01

Revision No. 02



F4-OPC 01: BCG Bulk and Formulation

Particle counter No.	Location
1	In-Feed to filling and stoppering machine
2	Vial Filling station near filling needles
3	Vial Stoppering Station
4	Lyophiliser Loading/ unloading LAF
5	Background Area (for Grade B)



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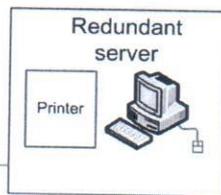


Annexure: 2 - Online Particle Counter System Architecture

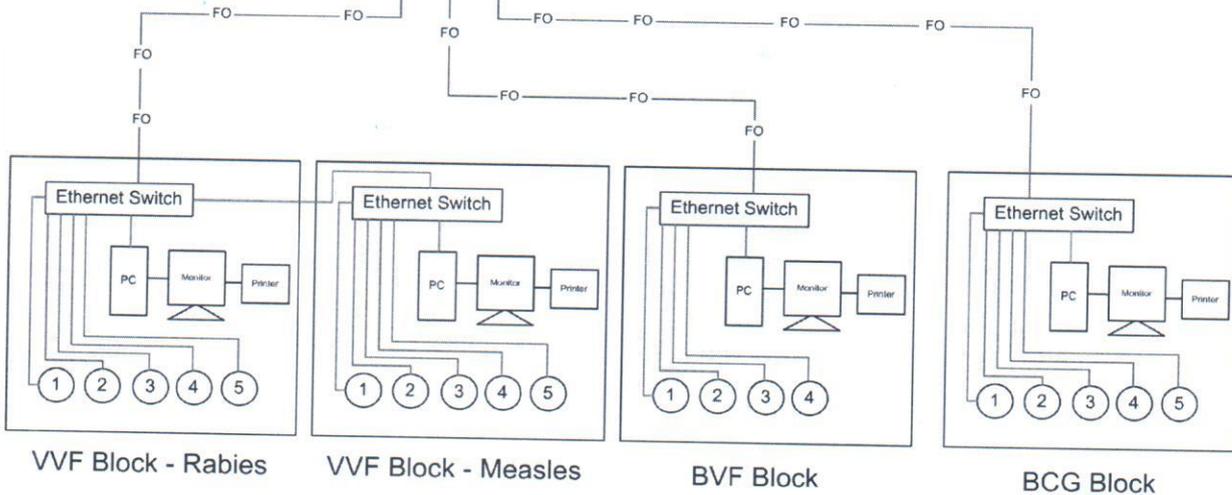
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Admin / QA / QC Block



Ethernet switch with optical ports 8 Nos.



① ② ③ ④ ⑤ → Online Particle Counters

FO → Fiber Optics Cable

→ PoE Cable

→ Cat 5e/Cat 6 Cable

Online Particle Counter System Architecture